

COVID-19 Vaccination Plan

MONTANA

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Section 1: COVID-9 Vaccination Preparedness Planning

A. The Montana Department of Public Health and Human Services (DPHHS) has exercised its mass vaccination and Medical Countermeasures (MCM) and Strategic National Stockpile (SNS) plans since the inception of the Public Health Emergency Preparedness (PHEP) program with the help of the CDC Cooperative Agreement created by the US Congress passing the Pandemic and All Hazards Preparedness Act in December of 2006. These MCM and SNS plans include vaccine distribution.

DPHHS allocates a portion of its grant funding to local and tribal health jurisdictions (LHJ) in return for completing assigned deliverables. Part of the deliverable requirements include writing, exercising, and updating their own MCM plans and Point of Dispensing (POD) procedures.

Montana has a decentralized government, meaning local and tribal governments are responsible for distributing and dispensing vaccines within their own jurisdictions. PHEP reviews these plans as part of deliverable requirements for the LHJs.

Montana's role is to receive, stage, and ship medical assets to public health agencies and other healthcare related facilities. PHEP ensures each jurisdiction keeps their distribution plans current, and partners with the Immunization (IZ) program to ensure at least one vaccination clinic is conducted annually as an exercise of those plans. DPHHS does not conduct its own vaccinations. State facilities with resident populations work with local public health departments to conduct closed clinics for residents and staff.

The 2009 H1N1 response for distributing vaccine was the first time Montana activated its MCM plan. The after-action reports (AAR) and subsequent improvement plans (IP) allowed program staff to make changes to the gaps observed ten years ago. Since then, the PHEP cooperative agreement has cycled twice. The funding agreement requires jurisdictions to hold full-scale exercises to test SNS and MCM plans. Montana conducted Big Sky Push 2 in 2014 with participation from all local and tribal health jurisdictions and planning partners. The ARR and IP led to adjustments to several plans, as does any exercise.

DPHHS held its latest full-scale exercise, Operation Oro y Plata Armis, in October 2019. This exercise also included all local and tribal jurisdictions and planning partners.

Both of the full-scale exercises and the H1N1 response were predicated with planning and mutual agreements with multiple partners. These partners included federal agencies such as US Health and Human Services and the US Marshall Service and the United States Postal Service (quasi-governmental). State government agencies included the Montana Disaster and Emergency Services (DES) and the Montana Highway Patrol. Private enterprises also participated, such as transport companies United Parcel Service (UPS), FedEx, Mergenthaler Transfer and Storage.

Planning partners for LHJs includes emergency managers, local law enforcement, pharmacies, hospitals and clinics, long term care centers, and private businesses, among others. Plans are supported by mutual aid agreements and memos of understanding (MOU).

DPHHS PHEP is currently working through its improvement plan developed from the 2019 full scale exercise that directly impacts distribution of medicine and medical material. Some of those gaps

have already been addressed through current operations for ordering and distribution of personal protective equipment (PPE) to Montana’s 58 county and tribal health jurisdictions.

In summary, the IP called for improvements in sharing essential elements of information (EEI) among partners, better verification of delivery points, more timely communication, information quality control, develop closer relationships with transport partners, and identifying back-up personnel for incident command positions.

Anticipated gaps for immediate action include:

- Written operating procedures for ordering, delivery, and tracking of COVID-19 vaccine (most of which is accomplished within this document)
- Just in time training protocols for COVID-19 vaccine specific activities
- Developed and targeted public information campaign focused on the COVID-19 vaccine for Montanans
 - Vaccine hesitancy among the public
 - Misinformation and rumors about COVID-19 vaccine among the public
 - Importance of starting with critical populations
 - Follow-through with second dose of vaccine

Shared challenges with local and tribal jurisdictions include the following

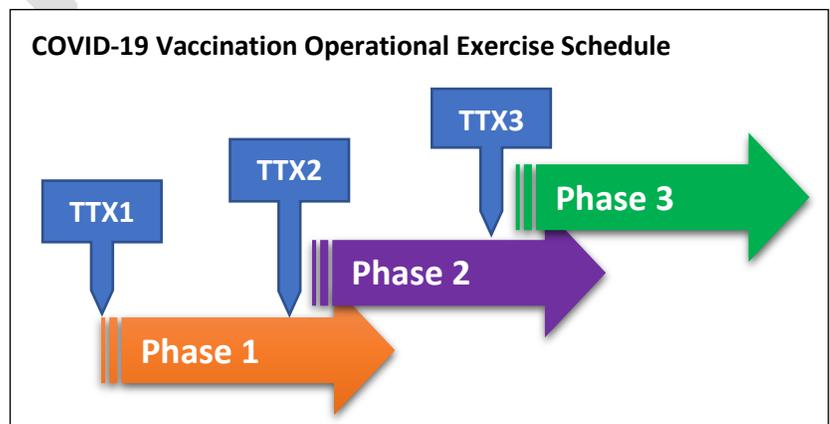
- Lack of personnel in smaller jurisdictions to dispense vaccine
- Supporting local public health agencies with justifying prioritized selections of critical populations to their local governments

B. Upon implementation of Montana’s COVID-19 Vaccine Strategy, and prior to the first shipment of vaccine, PHEP will design and execute a tabletop exercise (TTX) with representative participants. Artificialities of the scenario will include an accelerated timeline to cover operational expectations.

The resulting After-Action Report will drive an Improvement Plan (IP) will drive updates to the strategy document and refine procedural practices.

A TTX will proceed each phase of the operation (see Section 3). The AAR and IP will ensure the continuity of quality improvement and mitigate gaps discovered in operational planning. Because the dates for the release of vaccine is uncertain, specific dates cannot be determined.

In addition to the exercises, Incident Action Plans (IAP) for operational periods will address discovered issues and list improvement actions. This standard Incident Command Structure (ICS) practice is a built-in quality control method that meets the immediate needs of resolving issues throughout the campaign.



NOTE: Graph not scaled to actual dates.

Section 2: COVID-19 Organizational Structure and Partner Involvement

- A. COVID-19 vaccinations require collaboration and communication across multiple agencies, programs, and stakeholders. The State of Montana’s plan recognizes the importance of this collaborative response and is establishing two key advisory groups that will guide the effective vaccination effort. The operational hub of this effort will be located in DPHHS’s Immunization Section in the Communicable Disease Control and Prevention Bureau (CDCPB), which has historically been the operational center of other major immunization and communicable disease responses in the state. This work will be guided and assisted by both an internal Planning Advisory Group (reporting to the Governor’s Coronavirus Taskforce) as well as the Vaccination Plan Coordination Planning Team, which will be comprised of key community stakeholders from across Montana representing multiple entities outlined below. Of note, the lists below are not dispositive, as the State of Montana is focused on ensuring representation, communication, and collaboration throughout this process.
- B. The internal COVID-19 Vaccination Planning Advisory Group is comprised of subject matter experts in communicable disease, immunization, administrative direction, and public health emergency preparedness. This cross section of experts and Department leadership will be charged with core implementation as well as rapidly identifying challenges, issues, and operational issues requiring swift resolution and action.

COVID-19 Vaccination Planning Advisory Group

State Medical Officer
Medical Director, MT Department of Labor and Industry
Deputy Director, DPHHS
Public Information, DPHHS
Administrator, Communicable Disease & Laboratory Services Division
Bureau Chief, CDCPB
MT Disaster and Emergency Services/Governor’s Coronavirus Task Force
DPHHS Immunization Program
Vaccine Manager, Montana Immunization Program
Epidemiologists
Public Health Emergency Preparedness Section Supervisor
Healthcare Preparedness Program Supervisor

- C. The broader COVID-19 Vaccination Plan Coordination Team will be comprised of stakeholders from various sectors across the state, many of whom are established key COVID-19 crisis response partners with the state government and in their communities. Representation from at risk populations will be especially essential as Montana moves through key phases of the plan. Representatives will include, but are not limited to: health systems and hospitals, local health departments, representatives from tribal governments, urban Indian health centers, Indian Health Service, long-term care facilities, correctional facilities, emergency management services, rural health clinics, pharmacies, business and occupational health organizations, health insurance issuers and plans, organizations serving people with disabilities, education agencies and providers, churches and religious leaders and institutions, organizations serving racial and

ethnic minority groups, organizations serving people with limited English proficiency, and community representatives.

- D. Internal and external committee members are identified in each subsection above. DPHHS will work closely with key Montana representative entities to ensure individual representatives are identified.
- E. DPHHS fosters collaborative partnerships with counties, tribes, non-profit organizations, healthcare entities, and private businesses as standard operations. As a decentralized government, State agencies depend heavily on these partnerships to serve the people of Montana.

DPHHS will engage with these partners as part of the ongoing response to the COVID-19 pandemic. Key roles for DPHHS partners will be communication with their constituents and their partners. Working with those partners as part of strategic involvement will encourage earlier participation of critical populations. Frequent communications for each phase of the plan will keep the partners engaged and is necessary to keep their organizations and patrons fully informed.

- F. Government-to-government relations and communications with tribal nations and health partners are important and critical throughout this process. A Virtual Tribal Consultation on the vaccine planning was held on October 8, 2020, and included tribal governments, urban Indian health centers, and Indian Health Service. The COVID-19 Vaccination Plan Coordination Team will include representation from each of the following tribal and health entities to ensure unique perspective and expertise is heard:

- Indian Health Service, Angela Troutt
- Helena Indian Alliance, Todd Wilson
- All Nations Health Center, Elizabeth Williams
- Billings Urban Indian Health & Wellness Center, Kim Brown
- North American Indian Alliance, Shannon Parker
- Indian Family Health Clinic, TBD
- Little Shell Tribe, Molly Wendland
- Blackfeet Nation, Laura Upham
- Crow Nation, TBD
- Fort Peck Tribes, TBD
- Confederated Salish & Kootenai Tribes, TBD
- Fort Belknap, TBD
- Northern Cheyenne Tribe, Janet Wolfname

- G. DPHHS is committed to ensuring that all key partners—including critical and at-risk populations—are fully engaged throughout the COVID-19 vaccination process. As more fully described above, DPPHS is committed to engaging critical population partners through invitation and inclusion on the COVID-19 Vaccination Plan Coordination Team. Critical population representation includes, but is not limited to: long-term care facilities, tribal communities,

correctional and congregate settings, homeless shelters, community-based organizations, hospital systems, and pharmacies, among others.

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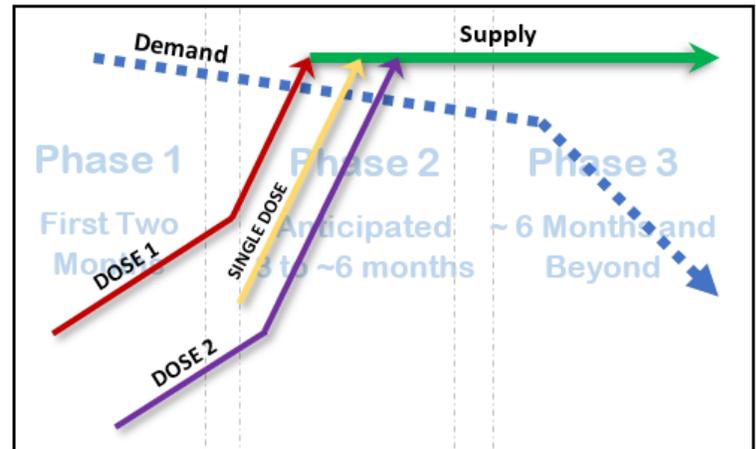
Section 3: Phased Approach to COVID-19 Vaccination

Operational Response Strategy

The COVID-19 vaccination campaign is already underway with national planning and pharmaceutical trials nearing completion. The CDC’s COVID-19 Healthcare Resilience Task Force has provided models and information on expected release and delivery of the vaccine. Based on their planning recommendations and guidance, DPHHS is adopting a three-phase approach for vaccine distribution operations. This strategic approach accounts for the overlap of work between phases.

NOTE: There are many dynamic factors on federal, state, and local levels that will impact the operations and delivery of the COVID-19 vaccine. The unforeseeable events that might impact this framework creates a cone of uncertainty, making planning difficult for future distribution of vaccine. This dynamic nature compels a framework approach that lends itself to shifting beyond currently defined timelines.

COVID-19 Vaccination Operational Outlook



NOTE: Graph not scaled to actual dates.

Phase 1: Targeted Critical Workforce; Limited Supply

First Two Months

The federal government will release stockpiled COVID-19 vaccines in anticipation of FDA approval. CDC has not indicated how much vaccine is allocated to Montana.

Goal: Maximize the limited supply of allocated vaccine to ensure essential response personnel and people at the highest risk of life-threatening infection receive at least the first dose within the first two months of initial distribution.

Activities

1. Enroll vaccine providers and collect initial vital data (see Section 5).
2. Determine critical populations and define essential response personnel (see Section 7).
3. Establish routine communication periods with providers.
4. Initiate vaccine orders to local and tribal health jurisdictions and their dispensing partners and engage tracking systems.
5. Begin routine reporting to CDC.
6. Initiate public information campaign.

Phase 2: Expanded Dispensing; Adequate Supply

Three to Approximately Six Months

The CDC will ship more vaccine doses as the FDA approves more formulations and supply increases. DPHHS will encourage providers to continue targeting critical workforce and begin to move forward with

defined prioritized groups (see Section 7). Second dose vaccines will be among the deliveries to complete courses for critical personnel.

Goal: Ensure access to COVID-19 vaccine for critical population members who were not vaccinated in Phase 1, provide second dosing for Phase 1 recipients, and expand availability to other prioritized groups.

Activities

1. Expand vaccine provider enrollment.
2. Continue tracking vaccine to ensure administration to critical populations and essential personnel.
3. Continue regular communications with LHJs with COVID-19 vaccine distribution operations.
4. Continue daily reporting to CDC.
5. Troubleshoot and solve vaccine tracking, shipping, and storage issues as presented.
6. Begin measurement of uptake among critical populations for operational planning.
7. Work with Public Information to counter any misinformation, overcome vaccine hesitation, and to update the public about vaccine availability.

Phase 3: Expand and Normalize Distribution for Public Dispensing; Sufficient Supply Six Months and Beyond

Focus for Phase 3 will shift to reaching Tier 5 populations. Vaccine producers should have manufactured enough to make it widely available. At this point, distributing and dispensing should be routine. The COVID-19 vaccine may become part of routine immunizations along with influenza and scheduled or recommended preventative injections. Projections for Phase 3 are highly dependent on event conditions and updated guidance and operational decisions from the CDC and FDA.

Goal: Make COVID-19 vaccine ordering and dispensing a routine process for providers and ensure equitable access across the entire population.

Activities

1. Continue regular communications with LHJs and enrolled providers to share operational changes and messaging.
2. Continue daily reporting to CDC.
3. Continue working with Public Information
4. Troubleshoot and solve vaccine tracking, ordering, shipping, and storage issues as presented.
5. Continue measurement of uptake among all populations for operational planning and public communications
6. Transition operational activities into routine daily functions.

Section 4: Critical Populations

A. Defining critical personnel in Montana is primarily a local function. However, the State will define the critical populations for the COVID-19 vaccine in accordance with federal guidance and ACIP recommendations. The vaccine may be a limited resource and a successful strategic framework for a mass vaccination campaign should follow ethical, yet practical, principles for fair and equitable allocation decisions.

State agencies provide program services to specifically defined critical populations, but LHJs along with public and private providers provide the direct services within the communities. LHJs meet regularly with community partners for preparedness planning and exercises. They also collaborate to hold vaccination clinics within their jurisdictions. Because the populations of individual jurisdictions are so small, locating and estimating critical populations within communities is not a difficult task, is already part of preparedness through PHEP, and will only need updating for vaccine planning. The State will assist by providing tools and information to help local planning for POD/clinic planning and to COVID-19 vaccine enrolled providers.

Populations of focus for initial COVID-19 vaccination will likely fall into four categories:

1. Critical infrastructure workforce (includes Healthcare Personnel (HCP) (see <https://www.cisa.gov/identifying-critical-infrastructure-during-covid-19>)
 - a. Healthcare personnel (i.e., paid and unpaid personnel working in healthcare settings, which may include vaccinators, pharmacy staff, ancillary staff, school nurses, and EMS personnel)
 - b. Other essential workers (see additional guidance from the Cybersecurity and Infrastructure Security Agency)
2. People at increased risk for severe COVID-19 illness
 - a. LTCF residents (i.e., nursing home, assisted living, independent living facility residents)
 - b. People with risk factors for severe COVID-19 illness (see <https://www.cdc.gov/coronavirus/2019-ncov/need-extra-precautions/people-with-medical-conditions.html>)
 - c. People 65 years of age and older
3. People at increased risk of acquiring or transmitting Covid-19
 - a. People from racial and ethnic minority groups
 - b. People from tribal communities
 - c. People who are incarcerated/detained in correctional facilities
 - d. People experiencing homelessness/living in shelters
 - e. People attending colleges/universities
 - f. People who work in educational settings (e.g., early learning centers, schools, and colleges/universities)
 - g. People living and working in other congregate settings
4. People with limited access to vaccination services

- a. People with limited access to routine vaccination services
- b. People living in rural communities
- c. People with disabilities
- d. People who are under- or uninsured

Population information comes from de-identified data provided by government and academic sources, including the following.

- Rural Health Information Hub. <https://www.ruralhealthinfo.org/states/montana>
- Rural Institute Montana Disability and Health Program, Community Profiles. http://mtdh.ruralinstitute.umt.edu/?page_id=6292
- Health Resources & Services Administration (HRSA) – MUAFind (Medically Underserved Areas/Populations). <https://data.hrsa.gov/tools/shortage-area/mua-find>
- US HHS Region 8 Community Profile Reports

Other information that might influence planning

- State epidemiology and laboratory testing
- Relevant CDC Morbidity and Mortality Weekly Reports (MMWR)
- Montana State University Extension Office publications
- Additional or updated guidance from CDC

B. Define and estimate numbers of persons in the critical infrastructure workforce

DPHHS works with datasets provided by the federal government and Montana’s Department of Labor & Industry (DLI). The Federal Cybersecurity and Infrastructure Security Agency (CISA) provides definitions for critical infrastructure workforce and specific guidance for COVID-19. DLI provides workforce information by occupation across the state and by county.

- Federal Cybersecurity and Infrastructure Security Agency. <https://www.cisa.gov/identifying-critical-infrastructure-during-covid-19>
- Montana Labor Market Information Dataset. <https://data.mt.gov/>

The healthcare systems workforce estimates can also be gathered through the Regional Healthcare Coalitions’ situational awareness program, Juvare.

C. Determining subset groups of critical populations if there is insufficient vaccine supply.

Planning vaccine distribution encompasses several factors. Allocations depend on current local spread/prevalence of COVID-19, vaccine production and availability, and the recommendations of the Advisory Committee on Immunization Practices (ACIP) with input from the National Academy of Medicine (NAM).

DPHHS will use the CDC’s Allocating and Targeting Pandemic Influenza Vaccine During an Influenza Pandemic (2018) and NAM’s Framework for Equitable Allocation of COVID-19 Vaccine (2020) (<http://nap.edu/25917>) to guide determination of critical population priority.

Populations of focus for COVID-19 vaccination will likely fall into five tiers:

Tier 1: Critical infrastructure workforce (includes Healthcare Personnel (HCP) See <https://www.cisa.gov/identifying-critical-infrastructure-during-covid-19> and

Allocating and Targeting Pandemic Influenza Vaccine During an Influenza Pandemic, <https://www.cdc.gov/flu/pandemic-resources/pdf/2018-Influenza-Guidance.pdf>

Tier 2: People at increased risk for severe COVID-19 illness (see <https://www.cdc.gov/coronavirus/2019-ncov/need-extra-precautions/people-with-medical-conditions.html>)

Tier 3: People at increased risk of acquiring or transmitting Covid-19

Tier 4: People with limited access to vaccination services

Tier 5: Healthy adults with limited or no underlying medical conditions

DPHHS is reserving the initial allocation of the limited supply of vaccine to the critical populations of Tier 1. See Figure 1 for CDC’s recommended prioritization for Tier 1 vaccination groups in an influenza pandemic.

Box 1. Prioritization of vaccination groups within Tier 1 based on availability of vaccine supply

Vaccine in short supply (Sufficient to vaccinate all of Tier 1)	Vaccine in extremely short supply (Insufficient to vaccinate all of Tier 1)
<p>All groups would be offered vaccine at the same time:</p> <ul style="list-style-type: none"> • Deployed and mission critical personnel • Critical healthcare (inpatient, outpatient, long-term care, pharmacists, pharmacy technicians) • Public health personnel • Emergency Medical Services (EMS) • Law enforcement • Fire services • Manufacturers of vaccine and antivirals • Pregnant women • Infants and toddlers 	<p>Proposed ranking of groups within Tier 1:</p> <ol style="list-style-type: none"> 1. Front-line inpatient and hospital-based health care personnel caring for sickest persons; health care personnel with highest risk of exposure 2. Deployed and mission critical personnel who play essential role in national security 3. Front-line EMS 4. Front-line outpatient health care personnel, pharmacists and pharmacy technicians, and public health personnel who provide immunizations and outpatient care 5. Front-line law enforcement and fire services personnel 6. Pregnant women and infants aged 6 -11 months old 7. Remaining groups in Tier 1 (includes other Tier 1 inpatient and outpatient healthcare personnel not vaccinated previously; public health; EMS, law enforcement, and fire services personnel; manufacturers of pandemic vaccine and antiviral drugs; and children aged 12-35 months old)

Figure 1. Allocating and Targeting Pandemic Influenza Vaccine During an Influenza

D. Points of contact (POCs) and communication methods for organizations, employers, or communities within critical population groups.

LHJs and DES coordinators develop preparedness plans with community leaders and representatives. Representatives include those organizations that serve access and functional need populations, healthcare, community officials, and local emergency management. LHJs build this collaboration as preparedness activities through requirements of the PHEP cooperative agreement. Planning community members also include Local Emergency Planning Committees (LEPC), Tribal Emergency Response Councils (TERC), non-government organizations (NGO), faith-based organizations, and VOAD/COAD. DPHHS will serve as the contact for state-level partners and organizations.

Section 5: COVID-19 Provider Recruitment and Enrollment

A. and B. Determining and Contacting Providers for Enrollment

The Immunization Program is obtaining primary contacts and emails for all potential Phase 1 COVID-19 vaccine providers identified as having the ability to reach Phase 1 critical populations. The Immunization Program will prioritize processing Phase 1 enrollments initially and progress to providers in other phases as the vaccination effort develops. The goal is to have providers enrolled and trained by the time vaccine is available to ship during that phase.

The Immunization Program will recruit potential providers by sending an email to the medical director or equivalent at the organization with the following attachments:

- COVID-19 Vaccine Program Provider Agreement and Profile
- Storage and Temperature Monitoring Addendum
- Redistribution Agreement
- imMTrax Memorandum of Agreement (MOA).

The Storage and Temperature Monitoring Addendum will describe the storage unit and temperature monitoring requirements for vaccine providers and a place to list the make and model of temperature monitoring equipment used for vaccine storage units at the location.

The body of the email will contain:

- A description of the program and request that they enroll as a COVID-19 vaccine provider
- The criteria for being a vaccine provider and how they meet that criteria
- Training and storage requirements
- Vaccine provider roles and responsibilities
- Critical populations for the current phase
- Instructions on how to enroll
- Instructions for submitting a mandatory imMTrax MOA, if not already an imMTrax participant
- A description of the Redistribution Agreement and how to become a vaccine redistributor
- Instructions to reply to the email with “Our organization is not interested in becoming a COVID-19 vaccine provider” if they are not interested in participating.

If we do not get a response to the first email within one week, we will attempt to call the point of contact at the organization. The goal is to receive either enrollment documents or an email or verbal confirmation that they are not interested within two weeks of initial contact.

C. and D. Collecting Enrollment Data; Verifying Credentials, Capabilities, & Capacities

The Immunization Program will distribute a COVID-19 Vaccine Program Provider Agreement and Profile, COVID-19 Vaccine Program Enrollment Addendum, and Redistribution Agreement to potential enrollees as fillable PDFs for them to complete using a computer and sign digitally. The completed and signed forms must be returned to the Immunization Program by email (hsiz@mt.gov) either through the “Submit” button on the form or by attaching the form to an email. Enrollment forms cannot be scanned or faxed.

Enrollment of approved vaccine providers will be completed within three business days of receiving the enrollment forms by the Immunization Program.

Enrollment documents will be processed as follows:

- 1) The VFC Quality Specialist will:
 - a. Inspect documents for completeness and accuracy; contact the organization for clarification and missing information or forms.
 - b. Ensure organizations with multiple locations have a provider agreement for each location.
 - c. Complete all “For official use only” fields and assign unique COVID-19 organization and location IDs following the instructions on the provide agreement so that all locations can be associated with the right organization.
 - d. Verify the medical licenses of providers listed in the provider profile are active and valid by looking them up in the Montana Department of Labor and Industry’s License Lookup database. Remand issues with licenses back to the organization for resolution, when necessary.
 - e. Forward submitted imMTrax MOAs to IIS staff for processing and entry into imMTrax.
 - f. Save inspected and completed enrollment forms on the shared drive in a folder called “Incoming Enrollment Documents” in a folder with the facility name.
- 2) The Vaccine Manager will review facility folders in the “Incoming Enrollment Documents” folder to confirm the listed vaccine storage units and temperature monitoring equipment meet requirements for COVID-19 vaccine in accordance with the manufacturer’s guidance, Emergency Use Authorization (EUA), and *CDC’s Vaccine Storage and Handling Toolkit*.
 - a. If equipment does not meet minimum requirements, the enrollment documents will be returned to the organization with guidance on how to meet requirements and instructions on how to re-submit. The facility folder will be moved to a “Pending” file. Organizations that cannot meet minimum storage unit and temperature monitoring requirements will not be approved as COVID-19 vaccine providers.
 - b. If equipment meets minimum requirements, the facility folder will be moved to an “Approved” folder. Approved enrollment forms will be retained for at least 3 years and made available to the CDC upon request.
- 3) The Vaccine Manager will compile the vaccination capacity, populations served, and vaccine storage capacity/capability information from the provider profiles for each location to be used in allocating vaccine. See Section 7.
- 4) The VFC Quality Specialist will enter approved facilities into imMTrax, the state immunization information system and the federal Vaccine Tracking System (VtrckS) marking them as COVID-19 vaccine providers where possible.
- 5) The VFC Quality Specialist will email the primary and backup vaccine coordinators, the medical director, and chief executive/fiduciary officer letting them know their enrollment is complete, what phase of the vaccination process they have been assigned, and what training requirements they must complete before receiving vaccine.

Immunization staff evaluates this process after Phase 1 enrollment to determine if an online form should be developed to collect enrollment information for subsequent phases.

Compiling and Reporting Enrollment Data

The Montana Immunization Program will extract data from completed, reviewed, and approved provider agreements collected on the fillable PDF provided by the CDC. The extracted data will be copied into a Provider Agreement Template Master CSV file, quality checked, and then uploaded to the Immunization Data Lake (IZDL) using the Partner Portal. Subsequent data extractions will be added to the master and the entire file will be uploaded to the IZDL twice a week Monday and Thursday by 9:00pm EST.

E. Training COVID-19 Vaccine Providers

Upon completion of their enrollment, the primary and backup vaccine coordinators at COVID-19 vaccine provider locations will receive an email detailing how to meet the training requirement. Anyone can take the Montana COVID-19 Vaccinator Training Module, but the primary and backup vaccine coordinator at each location will be required to complete the training and to disseminate the information to relevant staff at their facility. The facility cannot receive vaccine until the primary and backup vaccine coordinators have completed the training.

The Montana Immunization Program will train COVID-19 vaccination providers on the follow topics:

- ACIP COVID-19 vaccine recommendations, when available
- How to order and receive COVID-19 vaccine
- COVID-19 vaccine storage and handling (including transport requirements)
- How to administer vaccine, including reconstitution, use of adjuvants, appropriate needle size, anatomic sites for vaccine administration, avoiding shoulder injury with vaccine administration, etc.
- How to document and report vaccine administration via the jurisdiction's IIS or other external system
- How to manage vaccine inventory, including accessing and managing product expiration dates
- How to report vaccine inventory
- How to manage temperature excursions
- How to document and report vaccine wastage/spoilage
- Procedures for reporting moderate and severe adverse events as well as vaccine administration errors to VAERS
- Providing EUA fact sheets or VISs to vaccine recipients
- How to submit facility information for COVID-19 vaccination clinics to CDC's VaccineFinder (particularly for pharmacies or other high-volume vaccination providers/settings)

An all-awardee email from CDC NCIRD on September 21, 2020, indicated they are developing training material on many of the COVID-19 vaccine training topics listed above and they will make these materials available to jurisdictions and enrolled providers. We will review the CDC-provided materials as they become available, incorporate them into our training curriculum as appropriate,

and produce Montana-specific material to fill in any gaps. We will use the online learning platform Moodle to bring it all together into a comprehensive training program with the ability to track participation and completion. DPHHS requires the primary and backup vaccine coordinators at each location to complete the entire Moodle curriculum before they can receive vaccine at their facility. See Table 1 for details on the Moodle curriculum.

Table 1 Montana COVID-19 Vaccine Provider Training in Moodle

Topic	Training Material	Author
ACIP COVID-19 vaccine recommendations	Webinar and slide deck summary	CDC
Preparing and Administering COVID-19 Vaccine	COVID-19 training module and product summary sheets	CDC
Vaccine Storage, Handling, and Transport	COVID-19 training module, CDC Vaccine Storage and Handling Toolkit, Summary Sheets,	CDC
Determining BUD and Expiration Dates	BUD and expiration date tracking tools	CDC
Reporting Adverse Events and Administration Errors to VAERS	Online Videos -VAERS: Overview and Demo; VAERS: Online Reporting Demo	CDC
Providing and Managing EUAs and VISs	Forthcoming from CDC	CDC
Submitting COVID-19 Vaccination Clinic Information to CDC’s VaccineFinder	Forthcoming from CDC	CDC
Ordering and receiving COVID-19 vaccine	Online video and quick reference guide	Montana IZ Program
Managing and Reporting Temperature Excursions	Online video and quick reference guide	Montana IZ Program
Reporting Administered Doses	Online video and quick reference guide	Montana IZ Program
Managing and Reporting Vaccine Inventory	Online video and quick reference guide	Montana IZ Program
Documenting and Reporting Vaccine Wastage	Online video and quick reference guide	Montana IZ Program

In addition to the Moodle course, we will develop a “COVID-19 Vaccinator Resource” page to serve as a central location for COVID-19 vaccine training and information. It will have links to current CDC- and Montana-produced materials as well as a portal to our Moodle training module.

F. and G. Approving Vaccine Redistribution with Equity

All potential COVID-19 vaccinators will receive a Redistribution Agreement upon initial contact, and any provider can apply to become a vaccine redistributor. However, the Vaccine Manager will review submitted redistribution agreements and only approve those that meet the following criteria:

- High-volume storage capacity
- Ability to comply with cold chain requirements for storage and transport as defined by the manufacturer, the EUA, and *CDC Storage and Handling Toolkit*
- Ability to reach other locations in their organization or clinics needing smaller quantities of vaccine within an 8-hour day
- Willingness to assume financial responsibility for redistribution

- Ability to ensure locations receiving redistributed vaccine have an approved CDC COVID-19 Vaccination Program Provider Agreement

The Vaccine Manager will notify providers approved as redistributors and will keep a list of redistributors for use in allocating vaccines. See Section 7.

H. Recruiting and Enrolling Pharmacies Not Directly Enrolled by the CDC

Once the Montana Immunization Program is notified which pharmacies in Montana are being directly enrolled by the CDC, we will reach out to the remaining pharmacies who meet our COVID-19 vaccinator criteria as described above.

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Section 6: COVID-19 Vaccine Administration Capacity

- A. Montana's 2016 model study for pandemic influenza vaccination capacity suggested that it may take approximately 11 weeks for non-pharmacy providers and pharmacies to administer vaccines to 80% of the adult population in the state during a pandemic, assuming an optimum number of providers would enroll as pandemic vaccine providers. (Modeling Pandemic Influenza Vaccination Capacity for Adults - Montana Report, 2016) The study measured only capacity for adult vaccinations and social distancing protocol will impact throughput.

This model study for Montana encompassed the following assumptions, among others.

1. The vaccination campaign would take place during a severe pandemic, where public demand for vaccination would be extremely high and remain so throughout the vaccination campaign.
 2. All providers described in the model inputs would actually enroll, be eligible, and agree to participate in the pandemic vaccination program.
 3. Enrollment rate of 100% of health departments and hospitals, and 65% of doctor offices; 90% of chain pharmacies; 75% of supermarket and mass merchant pharmacies; and 50% of independent pharmacies.
 4. The rate of vaccine administration by all providers would be constant throughout the weeks of the vaccination campaign.
 5. 30 million vaccine doses could be distributed weekly with a pro rata allocation of doses by the Federal government to states.
 6. Linear ramp up time of 5 weeks for full vaccine administration capacity in the state.
 7. A lead time of 5.4 days between allocation and shipment of vaccines, based on historical data from the 2009 H1N1 Pandemic.
- B. Immunization staff will enhance the basic modeling from this study in several ways. Accurate collection of data from provider enrollment forms can narrow the vaccine administration capacities and inform allocations. More specific information coupled with new technology and web-based calculating tools will also assist creating more accurate estimates. The Immunization Program will use these tools with guidance from the CDC.

Broader outreach to providers in Montana is already underway in an effort to maximize enrollment. Coupled with information about the population each provider serves, the staffing available, potential throughput (already estimated through LHJ preparedness planning) and other ongoing routing vaccinations, the Immunization Program staff can estimate the administration capacity for the COVID-19 vaccine.

Section 7: COVID-19 Vaccine Allocation, Ordering, Distribution, and Inventory Management

A. Allocating Vaccine

The Planning and Coordination Team, with oversight by the Implementation Committee, will allocate vaccine to enrolled providers using the information from Sections 4, 5, and 6 of this document.

The Vaccine Manager will maintain a database of the following information for each COVID-19 vaccine location and make it available to help with allocation decisions.

Vaccination Capacity

- Number of patients/clients seen weekly: <18 years, 19–64 years, >65 years
- Number of unique patients seen per week on average
- Number of influenza vaccine doses administered during peak week of the 2019-2020 flu season
- Populations served

Storage Capability and Capacity

- Storage temperature range capabilities
- Number of multi-dose vials that can be stored

The VFC Quality Specialist will provide current inventory, doses administered, and wastage information for each location. Locations will reconcile vaccine inventory weekly to keep information as up to date as possible.

Federal and commercial partners receiving vaccine directly from the CDC will also provide information on current inventory and vaccine administration to inform allocation decisions.

B. Assessing Cold Chain Capability

Provider locations must meet the requirements listed in the Storage and Temperature Monitoring Addendum before the Immunization Program allows them to store COVID-19 vaccine.

As part of the enrollment process, the Vaccine Manager will review the make and model of vaccine storage and temperature monitoring equipment listed in the enrollment documents to ensure they are:

- CDC-recommended storage unit types
- Capable of holding proper vaccine storage temperatures
- Equipped with continuous monitoring digital thermometers with the following features:
 - Continuous recording devices that take readings at least every 30 minutes
 - Reads temperatures from a buffered probe
 - Displays current, minimum, and maximum temperatures
 - Generates temperature data that is reviewable, archivable, and able to be sent to the Immunization Program for review
 - Alarms to indicate temperatures outside proper vaccine storage temperatures

Providers who cannot meet these vaccine storage standards will not be allowed to enroll as COVID-19 vaccine providers.

C. Ordering Vaccine

During Phases 1 and 2 when vaccine supply is limited, COVID-19 vaccine providers will not directly order vaccines. The Immunization Program will hand-key orders into VtrckS for them following the process below.

1. Each week, the Planning Advisory Group, with input from the Plan Coordination Team, will review the vaccine available and apportion it between enrolled providers.
2. The Group will communicate to the VFC Quality Specialist the number of doses to be shipped to each location.
3. The VFC Quality Specialist will hand-key the orders into VtrckS.
4. Immediately after the order is placed, the VFC Quality Specialist will email the primary and backup vaccine coordinator at the receiving location to let them know a COVID-19 vaccine order has been placed and an estimated arrival date.
5. When the VFC Quality Specialist is notified by the CDC that the vaccine has shipped, she will again email the primary and backup vaccine coordinators at the location that a shipment will arrive that day and hand-key the inventory into the appropriate location in imMTrax.

As required by the enrollment agreement, COVID-19 vaccine providers will immediately communicate changes in contact information and shipping data to the VFC Quality Specialist. Upon receipt of this information, the VFC Quality Specialist will update imMTrax, VtrckS, and all COVID-19 vaccine provider databases with the updated information. The Immunization Program will develop a checklist to facilitate this process.

D. Vaccine Transfers

The Immunization Program may occasionally allow local transport of vaccines from one location to another, outside of established Redistribution Agreements, as long as cold chain requirements are maintained. Staff will train providers on how to submit transfers for approval and maintain cold chain during transport in the Montana COVID-19 Vaccine Provider Training in Moodle.

- Locations can only transfer vaccine between currently enrolled COVID-19 vaccine providers.
- Locations cannot transfer opened, multi-dose vials.
- Locations must follow the current guidance for cold chain management during transport of COVID-19 vaccine as described in the manufacturer's prescribing information, the EUA for the vaccine, and the *CDC Vaccine Storage and Handling Toolkit*.
- Transfers must be limited to those that can be personally carried and where the vaccine can reach an approved storage unit within eight hours or a regular business day.
- Vaccine transfers must be approved by the Immunization Program prior to physically exchanging the vaccine.
- Provider must submit all transfer requests in imMTrax and notify the VFC Quality Specialist by email that a transfer request has been submitted.
- The VFC Quality Specialist will review transfers for compliance with the requirements listed above and, if approved, will email the submitting and receiving location saying the vaccine is authorized for transfer and provide transport guidance for the vaccine being moved.

E. Monitoring Vaccine Inventory and Wastage

DPHHS will require COVID-19 vaccine providers to manage their inventory in imMTrax. Providers will learn inventory management in the Montana COVID-19 Vaccine Provider Training in Moodle.

- The VFC Quality Specialist enters the doses of vaccine shipped to each location into their imMTrax inventory
- Vaccine providers are required to reconcile their inventory each Friday by removing doses administered from their current inventory. Weekly reconciliation is necessary to provide current stocking levels to the Planning and Coordination Team for making allocation decisions
- The VFC Quality Specialist will submit current inventory for all COVID-19 vaccine providers in VtrcKS weekly each Monday
- Vaccines distributed under an EUA will not have an accurate expiration date in imMTrax, but will have a “placeholder” date of 12/31/9999 instead; Current guidance in the EUA and BUD tracking tools from the CDC should be used to determine expiration dates

Providers will report vaccine wastage to the Immunization Program by submitting a Wasted and Expired form to the VFC Quality Specialist. The Montana Immunization Program will track wastage by location. The Immunization Program will develop a process for recovering (returning) COVID-19 vaccine when the CDC communicates details guidance.

Section 8: COVID-19 Vaccine Storage and Handling

A. Assessing Cold Chain Capabilities

As part of the enrollment process, providers must submit a Storage and Temperature Monitoring Addendum. The Addendum describes the equipment requirements for storing COVID-19 vaccine and a place to list the make and model of their storage units and temperature monitoring equipment at each location.

The Vaccine Manager will review information provided on the Addendum to ensure the following:

1. Equipment meets vaccine manufacturer, EUA, and CDC-requirements for the vaccines of interest
2. Storage units are capable of holding proper vaccine storage temperatures for the vaccines
3. Storage units are equipped with a continuous monitoring digital thermometer with the following features
 - a. Continuous recording device that take readings at least every 30 minutes
 - b. Reads temperatures from a buffered probe
 - c. Displays current, minimum, and maximum temperatures
 - d. Generates temperature data that is reviewable, archivable, and able to be sent to the Immunization Program for review
 - e. Alarms to indicate temperatures outside proper vaccine storage temperatures

If equipment does not meet minimum requirements, the Vaccine Manager will return the enrollment documents to the organization with guidance on how to meet resolve the issues and instructions on how to re-submit. Providers who cannot meet these vaccine storage standards will not be allowed to enroll as COVID-19 vaccine providers.

If equipment meets minimum requirements, the Vaccine Manager will approve facility to store the vaccines within their capabilities and the enrollment will proceed.

All COVID-19 vaccine provider locations must enroll through the Immunization Program as described in this plan and have their storage and temperature monitoring capability approved by the Vaccine Manager, including those approved to redistribute vaccine and locations that will receive vaccine from a redistributor.

The Vaccine Manager will track storage and temperature monitoring capabilities of each enrolled location and make it available to the Planning and Coordination Team for use in making allocation decisions.

B. Ensuring Adherence to Cold Chain Requirements

All providers must complete the COVID-19 Vaccine Provider Training course in Moodle, which will include general storage and temperature monitoring guidance and vaccine-specific requirements based on forthcoming guidance from the manufacturers, EUA, and *CDC Vaccine Storage and Handling Toolkit*.

In addition to any vaccine-specific cold chain requirements (yet to be determined), providers will be required to:

- Document minimum and maximum temperature every morning their facility is open and prior to any major vaccination event
- Immediately report temperature excursions to the Immunization Program by submitting an online Vaccine Incident Report and not using vaccine affected by the excursion until the Immunization Program clears it for use
- Archive electronic temperature data and minimum/maximum temperature documentation for all COVID-19 storage units for three years and make it available to the Immunization Program upon request

Satellite, Temporary, and Off-Site Clinic Storage and Handling Considerations

Satellite, temporary, or off-site clinics that require vaccine transport from a central location need enhanced storage and handling practices. The DPHHS COVID-19 Vaccine Provider Training Course in Moodle will train providers on proper vaccine transport procedures based on the COVID-19 addendum to CDC's *Vaccine Storage and Handling Toolkit*.

The Storage and Temperature Monitoring Addendum collected during enrollment will describe the requirements for COVID-19 vaccine transport and have a place to list the transport capability of the provider location. The Vaccine Manager will review the equipment to ensure it meets requirements and either approve or deny the provider as a COVID-19 vaccine transporter.

In addition to any vaccine-specific requirements, providers holding satellite, temporary, or off-site clinics will be required to:

- Limit the amount of COVID-19 vaccine transported to the location based on the anticipated number of vaccine recipients
- Transport vaccine using proper equipment and procedures outlined in the COVID-19 Addendum to CDC's *Vaccine Storage and Handling Toolkit*
- Store vaccine at the appropriate temperature throughout the day of the clinic
- Review and document temperatures according to the COVID-19 addendum to CDC's *Vaccine Storage and Handling Toolkit*
- Assess temperature data at the end of the day before returning vaccine to fixed storage
- Immediately report temperature excursions to the Immunization Program by submitting an online Vaccine Incident Report and not using or discarding the affected vaccine until receiving instructions

Section 9: COVID-19 Vaccine Administration Documentation and Reporting

- A.** Montana DPHHS offers several systems and methods for data collection to vaccine providers. Immunization staff will determine which to use based on the unique facility needs and capabilities.
- IIS – direct entry, HL7 submissions
 - Vaccine Administration Management System (VAMS) – provided by CDC, is available for direct entry, reporting to the IZ Gateway, and subsequently to the IIS
 - External Web Application – PrepMod (pending), available for direct entry reporting to the IIS
 - Flat file submission (where direct entry or HL7 submission is not feasible) based on provided template with required data elements; Files submitted will be validated and uploaded into the IIS
 - Paper administration record received via fax based on provided template with required data elements; This method is for emergency use and only appropriate where internet or computer access becomes unavailable, such as a prolonged power outage
- B.** COVID-19 required vaccine information will be collected through the IIS and sent to the CDC via the IZ Gateway. If this method is not available, we will compile a CSV file of the required data elements and send it to CDC via an approved, secure method.
- C.** Each facility administering COVID-19 vaccine that is required to report every 24 hours will be contacted by Immunization Program staff to establish primary and back-up methods for data submission. Regardless of methods identified, Immunization Staff will provide each facility instructions and resources for flat file (Excel) and paper record submission in case of emergency or failed primary or back-up reporting method. Immunization staff will document the methods identified and maintain them for reference.
- Immunization Program staff will contact all facilities to determine if the providers will be, or expect to be, administering COVID-19 vaccine at a satellite, temporary, or off-site clinic setting. If yes, the facility will provide the primary and back-up method for data submission in that setting.
 - Facilities submitting data via direct data entry or HL7 into the IIS or PrepMod will be provided instructional resources and documents created by IIS staff.
 - Facilities submitting data via direct data entry into the IIS or PrepMod will be offered individual and group web-based training to review functionality and requirements by IIS staff.
 - Immunization staff will encourage all facilities to establish and familiarize themselves with their respective reporting method prior to use, along with basic troubleshooting information available and phone/email contacts for help desk services based on reporting method used.
- D.** Part of the communication with facilities will determine which will, or expect to, administer COVID-19 vaccine at a satellite, temporary, or off-site clinic setting. If yes, the facility will provide the primary and back-up method for data submission in that setting.

Immunization staff will encourage all satellite, temporary, or off-site clinic settings to establish and familiarize themselves with their respective reporting method prior to use, along with basic troubleshooting information available, and phone/email contacts for help desk services based on reporting method used.

- E. Immunization Program staff will compare doses reported as administered to doses reported to the IIS in the same evaluation period. The staff will contact facilities directly to request investigation and resolution when they find discrepancies. Staff will directly contact facilities not reporting any vaccination data for 2 consecutive business days to determine any gaps in reporting.
- F. The State of Montana expects to obtain access to an IIS connected COVID-19 Data Dashboard, currently under development with Scientific Technologies Corporation (STC). This vendor estimates making a dashboard available by early November. While the specifications are not yet available, the dashboard is expected to display vaccination administration and coverage assessment data by county and defined population groups. Numerators and denominators will be available. All data will be exportable.

Immunization Program staff will utilize the Coverage Rate Report tool within the IIS to review vaccination series completion coverage for persons receiving COVID-19 vaccine, by type.

Section 10: COVID-19 Vaccination Second-Dose Reminders

- A. Montana’s Immunization Information System (IIS) has a Reminder/Recall module available to all users with permissions higher than read only. The Immunization Program will provide instructional materials specific to COVID-19 reminder and recall functions in the IIS to all participating facilities.

Montana’s IIS Coverage Rate Report includes an option to export patient lists based on vaccine selected. The tool can be used to obtain a list of patients who have received the first dose and includes basic information such as primary phone number.

Immunization Program staff will encourage VAMS users to familiarize and utilize any reminder and recall functionality available in that system.

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Section 11: COVID-19 Requirements for IISs or Other External Systems

A. Montana's IIS has a mass immunization data entry module which facilitates rapid information input. The module requires inventory and lot management within the IIS. All administering facilities will have access to the module. The module is contained within the IIS and requires computer, internet access, and current credentials.

B. Montana's IIS captures the following information.

- Date of Birth
- Sex
- Race
- Ethnicity
- Address
- Phone Number
- Email
- Population Group (in development)

C. Montana uses STC's IWEB, PHC-Hub, and VOMS applications to comprise the cloud hosted IIS. PHC-Hub is the interoperability tool and can receive VXU messages and return QBP messages, including forecasting (Z44) where requested.

The IIS has several report and output capabilities available, including doses administered. The State of Montana expects to obtain access to an IIS connected COVID-19 Data Dashboard, currently under development. The STC dashboard will display vaccination administration and coverage assessment data by county and defined population groups. Numerators and denominators will be available. All data will be exportable.

D. The DPHHS Immunization Section is currently contacting pharmacies, long-term care centers, and nursing homes not currently submitting data to the IIS to offer enrollment to establish their locations and respective users as COVID-19 vaccine providers.

E. CONNECT - Credentials have been provided to the American Immunization Registry Association (AIRA) for the Production and Staging environments. Connectivity for VXU submissions has been established and confirmed in both environments.

SHARE - STC is currently coordinating needed certificate updates to facilitate the CONNECT options and expected to be in place by 10/16/2020, pending legal approval APHL and Interjurisdictional Agreements (below).

F. Montana has completed the Association of Public Health Laboratories (APHL) Data Use Agreement for the CONNECT component of the IZ Gateway. Montana is in the process of amending the APHL agreement to include the SHARE component.

Per CDC, this data use agreement is not yet finalized or available for legal review.

The Memorandum of Understanding is in legal review

- G.** In case of internal network outages, the Immunization Program staff will provide all facilities with a PDF file complete with required fields to use for data collection. Vaccine providers will print an adequate number of copies of the document and store as an emergency method.

Immunization Program staff will distribute an Excel spreadsheet complete with required fields to use for data entry and submission to all COVID-19 vaccine providers. Instructions for using these spreadsheets include saving copies to the internal drive of any computer or device they use for data collection to ensure it is readily available.

- H.** DPHHS Immunization Program staff will provide specific information on data entry expectations and requirements to all submitting facilities. Staff will compare administration dates with insertion dates into the IIS for all providers. Deviations outside 24 hours will be evaluated to determine outreach and improvements.

Staff will evaluate facilities or organizations administering COVID-19 vaccines and submitting via HL7, including the IZ Gateway, VAMS, and PrepMod, to ensure adherence to CDC-provided required fields. This will allow for various compliance reports to be used for analysis and individualized follow up.

Immunization Section staff monitor all submitting organization interfaces daily for errors to prevent data not being applied to the IIS. Communication between IIS staff and the submitting facility will ensure correction and resubmission. Facilities entering data manually through the IIS must complete the required fields.

IIS staff will run Provider Error and Warning Reports weekly to evaluate completion or validity of data elements submitted. Facilities found to be submitting patient/vaccination data at a threshold less than 97% for required fields will receive individual follow-up by IIS staff.

Staff will also directly contact facilities who fail to report any vaccination data for two consecutive business days to determine any gaps in reporting.

IIS and contract staff will manage and process any outstanding records held for duplicate review for all COVID-19 administering locations daily.

Section 12: COVID-19 Vaccination Program Communication

A. The Immunization Section will develop communications for guidance and information intended for COVID-19 vaccine providers. DPHHS public messaging is coordinated through the department's Public Information Officer (PIO) with IZ SME guidance. All communications are subject to the DPHHS Communications Policy in addition to the Governor's Coronavirus Task Force Joint Information Center.

DPHHS recognizes there are consistencies to public messaging concepts throughout all three phases of the COVID-19 vaccine program. Several of the elements will not change or will only change minimally. These static items are the audiences, modes of communication, and information sources.

Audiences:

- Critical infrastructure workforce (includes Healthcare Personnel)
- People at increased risk for severe COVID-19 illness and acquiring or transmitting Covid-19
- Educators
- Employers
- Local and Tribal governments
- General Population

Information resources:

- CDC guidance and information
- DPHHS Subject Matter Experts
- DPHHS Communications Policy
- COVID-19 One-Stop Shop Toolkits (in anticipation that COVID-19 vaccine informational materials will be added. <https://www.cdc.gov/coronavirus/2019-ncov/communication/toolkits/index.html>)
- World Health Organization Vaccine Safety Events: Managing the Communications Response https://www.euro.who.int/_data/assets/pdf_file/0007/187171/Vaccine-Safety-Events-managing-the-communications-response-final.pdf
- Enrolled COVID-19 vaccine Providers
- Local and Tribal Health Jurisdictions
- Pharmaceutical COVID-19 vaccine producers
- Other Federal sources

Modes of Communication

- Web and Social Media
- Hotline
- Public meetings
- Fact Sheets
- Radio and TV Broadcast
- Print publications

- Letters

Messaging might shift or take a different direction as the campaign progresses. This creates a cone of uncertainty for anticipated messages, and DPHHS acknowledges any variety of factors can re-prioritize message purpose and goals. Thus, the following objectives are current as of the creation of this document and remain only as general concepts. More key messages will develop as the PIO and subject matter experts continue to meet and discuss options with leadership.

Phase 1: Targeted Critical Workforce; Limited Vaccine Supply

First Two Months

Objective: Notify the public of the arrival of vaccine into the state and introduce the plan for distribution and the reasons supporting it.

Key Messages:

1. Montana has received its first shipment of vaccine.
2. A defined critical workforce will be the first to receive vaccinations
3. Limited supply of the vaccine at this time requires Montana to take a prioritized and planned approach to distributing and dispensing the vaccine.
4. Continue to social distance, wear masks, and wash hands.
5. Counter any misinformation about the safety or efficacy of the vaccine

Phase 2: Second Dose to Critical Populations and Expanded Dispensing

Three to Approximately Six Months

Objective: Notify the public of the increase of vaccine in the state and is available to an expanded group of at-risk populations and some providers can now offer the medicine.

Key Messages:

1. Montana has received its additional vaccine which is prioritized for critical populations at risk for severe consequences if infected with COVID-19.
2. Reminder of the roll-out plan for vaccine and describe eligible critical populations.
3. Provide information about providers offering vaccine.
4. Counter any misinformation about the safety or efficacy of the vaccine.
5. Continue to social distance, wear masks, and wash hands.
6. Provide encouragement and show empathy for those still waiting for the vaccine.

Phase 3: Expand and Normalize Continued Distribution for Public Dispensing

Six Months and Beyond

Objective: Continue regular encouraging and positive communication for everyone to receive both doses of the vaccine.

Key Messages:

1. There is an adequate supply of vaccine available, so go to your provider for a free injection and reminder for second dose.

2. Encourage wide-spread acceptance of the vaccine to return to a robust economy and return to normal life.
3. Provide information about providers offering vaccine.
4. Counter any misinformation about the safety or efficacy of the vaccine.

B. DPHHS PHEP maintains a Public Health Crisis and Emergency Risk Communications Annex as part of the department's EOP. The Annex encompasses guides and procedures based on the CDC's CERC and its principles. A toolbox document contains templates and instructions for rapid situational analysis, message development, audience identification, and delivery modes. Accompanying the toolbox is an immediate response template to quickly plan and execute a response to emergency situations.

Emergency communications are led by the DPHHS Public Information Officer. Two staff trained in the Advanced Public Information Officer: Health & Hospital Emergencies course at the Center for Domestic Preparedness.

The expedited process for emergency response, in brief, includes

1. Rapid situation assessment
2. Identify the audiences
3. Determine the communication methods
4. Develop immediate key messages
5. Focus on message integrity

A schedule of updates for the emergency is developed after the initial response. Even if no new information is available, the update event occurs to reinforce previous messaging or to add detail to the current information, which will demonstrate transparency.

All crisis and emergency messages are subject to the DPHHS Communications Policy.

Section 13: Regulatory Considerations for COVID-19 Vaccination

- A. The Immunization Program nurse consultant will review the EUA and VISs and training provided by CDC and the ACIP and develop training modules for the mandatory Moodle training for COVID-19 Vaccine Providers on how to locate, understand, and distribute EUA fact sheets and VISs.
- B. The mandatory Moodle training, as described in Section 5-E, will inform providers where to find the EUA and VIS documents for each COVID-19 vaccine, and we will link to these documents from our Montana COVID-19 Vaccinator Resource webpage.

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Section 14: COVID-19 Vaccine Safety Monitoring

Instructions:

- A. The Montana Immunization Program nurse consultant is the main point of contact for vaccine safety and VAERS reporting questions. The nurse consultant will develop a section in the mandatory Moodle training, as described in Section 5-E, on the requirements and process for reporting adverse events following any COVID-19 vaccination to VAERS.

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Section 15: COVID-19 Vaccination Program Monitoring

Monitoring Progress in COVID-19 Vaccination Program implementation

Provider enrollment

This will be measured by the number of providers engaged and the number of providers enrolled to participate in the vaccination program.

Access to COVID-19 vaccination services

This will be measured by the uptake of populations served, listed by the providers.

IIS Performance

The IIS manager, located in the Montana Immunization Program, will monitor IIS performance and enrollment by ensuring that systems are working properly. IIS Staff will monitor submissions daily and work with COVID-19 providers if errors in data submissions are found.

Data reporting to CDC

This will be measured by meeting the scheduled reporting goals outlined in operational procedures.

Provider-level data reporting

This will be measured by evaluating the number of follow-up contacts made to enrolled facilities or organizations for not meeting acceptable frequency or not providing information in the required data categories.

Vaccine ordering and distribution

This will be measured by tracking the orders and distribution of COVID-19 vaccine to enrolled providers.

2-dose COVID-19 vaccination coverage

This will be measured by tracking the orders and distribution of COVID-19 vaccine to enrolled providers needed to administer second doses.

Budget, Staffing, and Supplies

The Immunization Section Supervisor along with the PHEP section supervisor will monitor budget, staffing and supplies associated with the COVID-19 vaccination response. Any deficiencies in any of these categories will be reported to leadership during internal planning meetings.

Communication

All public communications must comply with by the DPHHS Communications Policy.

Local-level situational awareness

DPHHS Immunization Section, PHEP, and CDEpi conduct regularly teleconference meetings with local and tribal jurisdictions regarding their COVID-19 pandemic response operations. Agendas include exchange of information and discussions of operational updates. As a decentralized state, these meetings are voluntary and collaborative in nature.

COVID-19 Vaccination Program metrics

COVID-19 vaccination program metrics, including provider enrollment, doses distributed and administered, and vaccine coverage by jurisdiction will be calculated using the state's IIS. Relevant data will be shared using the Department's Coronavirus page located at <https://dphhs.mt.gov/publichealth/cdepi/diseases/coronavirusmt>.

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Appendix

Resources

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Initialisms

AAR/IP	After Action Report/Improvement Plan
ACIP	Advisory Committee on Immunization Practices
ASTHO	Association of State and Territorial Health Officials
CDC	Centers for Disease Control and Prevention
CDEpi	Communicable Disease Epidemiology Section (DPHHS)
CISA	Cybersecurity & Infrastructure Security Agency
DES	Disaster and Emergency Services Division of Montana
DID	De-Identified Data

DPHHS	Montana Department of Public Health and Human Services
DUA	Data Use Agreement
EOP	Emergency Operations Plan
ESF8	Emergency Support Function Public Health and Medical Services
EUA	Emergency Use Authorization
FDA	U.S. Food and Drug Administration
HHS	U.S. Department of Health and Human Services
HPP	Healthcare Preparedness Program
ICS	Incident Command Structure
IIS	Immunization Information Systems
imMTrax	Montana's IIS
IZ	Immunization
JITT	Just in Time Training
LHJ	Local Health Jurisdiction
MCM	Medical Countermeasures
MCMD	Medical Countermeasures and Distribution
MOA	Memorandum of Agreement
MOU	Memorandum of Understanding
NAM	National Academies of Medicine
NPI	Non-Pharmaceutical Intervention
NRF	National Response Framework
PAHPA	Pandemic and All Hazards Preparedness Act
PHEP	Public Health Emergency Preparedness
PHL	Public Health Laboratory
POD	Point of Dispensing
PPRI	Privacy-Preserving Record Linkage
SNS	Strategic National Stockpile
VAMS	Vaccine Administration Management System
VTrckS	Vaccine Tracking System